IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-cv-00560 (RGA)
MICRO LABS LTD., MICRO LABS USA INC.,	)	
Defendants	)	

DEFENDANTS' MICRO LABS LTD. AND MICRO LABS USA, INC.
ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Micro Labs Ltd. and Micro Labs USA, Inc. (collectively, "Micro Labs"), by their undersigned counsel, for their Answer to the Complaint filed by Bayer Intellectual Property GmbH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc. (collectively, "Plaintiffs"), state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Micro Labs denies all allegations in Plaintiffs' Complaint except those specifically admitted below:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Micro Labs Ltd. and Micro Labs USA Inc. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218.

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent any response is required, Micro Labs admits Plaintiffs purport to bring this action for infringement under the patent laws of the United States, Title 35, United States Code, of

United States Patent No. 9,539,218 ("the '218 patent"). Micro Labs admits that Micro Labs Ltd. filed an Abbreviated New Drug Application ("ANDA") concerning rivaroxaban tablets. Micro Labs denies any and all remaining allegations of Paragraph 1.

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

ANSWER: Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2, and on that basis denies these allegations.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

ANSWER: Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3, and on that basis denies these allegations.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

ANSWER: Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 4, and on that basis denies these allegations.

Micro Labs

5. On information and belief, Defendant Micro Labs Ltd. is a corporation organized and existing under the laws of India, with a place of business at 27 Race Course Road, Bangalore 560 001, India.

ANSWER: Admitted.

6. On information and belief, Defendant Micro Labs USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a place of business at 104 Carnegie Ctr., Suite 216, Princeton, New Jersey.

ANSWER: Admitted.

7. On information and belief, Defendant Micro Labs USA Inc. is a wholly-owned subsidiary of Micro Labs Ltd., and is controlled and dominated by Micro Labs Ltd.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Micro Labs USA, Inc. is a wholly-owned subsidiary of Micro Labs Ltd. Micro Labs denies any and all remaining allegations of Paragraph 7.

8. On information and belief, Micro Labs Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Micro Labs Ltd., acting in concert with Micro Labs USA Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Micro Labs Ltd., acting in concert with Micro Labs USA Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Micro Labs Ltd. manufactures, markets, distributes, offers for sale, and sells generic drug products; and admits that Micro Labs Ltd. has filed ANDAs and Paragraph IV Certifications with the U.S. Food and

Drug Administration ("FDA"). Micro Labs denies any and all remaining allegations of Paragraph 8.

9. On information and belief, and consistent with their practice with respect to other generic products, Micro Labs Ltd. and Micro Labs USA Inc. acted in concert to prepare and submit ANDA No. 208334 for Micro Labs Ltd.'s 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Micro Labs' ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Micro Labs Ltd.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Micro Labs Ltd. submitted ANDA No. 208334 for Micro Labs Ltd.'s 10 mg, 15 mg, and 20 mg rivaroxaban tablets. Micro Labs denies any and all remaining allegations of Paragraph 9.

10. On information and belief, Micro Labs Ltd. and Micro Labs USA Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Micro Labs' ANDA Products at issue.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Micro Labs denies any and all remaining allegations of Paragraph 10.

11. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs Ltd. and Micro Labs USA Inc. will act in concert to market, distribute, offer for sale, and sell Micro Labs' ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Micro Labs."

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of

the parties and the Court, Micro Labs does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Micro Labs denies any and all remaining allegations of Paragraph 11.

12. On information and belief, Micro Labs prepared and submitted ANDA No. 208334 for Micro Labs' 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Micro Labs' ANDA Products").

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Micro Labs Ltd. is the applicant for ANDA No. 208334 for 10 mg, 15 mg, and 20 mg rivaroxaban tablets, and Micro Labs USA Inc. is the authorized agent for the ANDA. Micro Labs denies any and all remaining allegations of Paragraph 12.

13. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs will market, distribute, offer for sale, and sell Micro Labs' ANDA Products throughout the United States and within Delaware.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

14. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

JURISDICTION

15. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

ANSWER: Micro Labs incorporates each of its answers to Paragraphs 1-14 as if fully set forth herein.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer may be required, Micro Labs admits that subject matter jurisdiction is proper, if at all, solely for Plaintiffs' purported claim against Micro Labs asserted under 35 U.S.C. § 271(e)(2). Micro Labs denies any and all remaining allegations of Paragraph 16.

17. In addition, this Court has personal jurisdiction over Micro Labs because, among other things, on information and belief: (1) Micro Labs has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Micro Labs' ANDA Products in the United States, including in Delaware; and (2) Micro Labs will market, distribute, offer for sale, and/or sell Micro Labs' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208334, and will derive substantial revenue from the use or consumption of Micro Labs' ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208334 is approved, the generic Micro Labs products charged with infringing the '218 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Micro Labs denies any and all remaining allegations of Paragraph 17.

18. Micro Labs has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of ANDAs, including C.A. No. 15-902 involving the same ANDA at issue here, and it has filed counterclaims in such cases.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest personal jurisdiction in this Judicial

District for the limited purposes of this action only. Micro Labs denies any and all remaining allegations of Paragraph 18.

VENUE

19. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b)

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies any and all remaining allegations of Paragraph 19.

FACTUAL BACKGROUND

20. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. XARELTO® is available as tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

ANSWER: Micro Labs admits that information publicly available in the records of the FDA for New Drug Application ("NDA") No. 022406 for rivaroxaban 10 mg, 15 mg, and 20 mg tablets, indicates that the rivaroxaban 10 mg, 15 mg, and 20 mg tablets that are the subject of the NDA have the proprietary name Xarelto®, and are indicated for treatment of pulmonary embolism (PE), treatment of deep vein thrombosis (DVT), reduction in the risk of recurrence of DVT and PE, prophylaxis of DVT, and reducing the risk of stroke and systemic embolism; and reduction in the risk of recurrence of DVT and PE. Micro Labs denies any and all remaining allegations of Paragraph 20.

21. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

ANSWER: Micro Labs admits that information publicly available in the records of the FDA indicates NDA No. 022406 has been approved by the FDA, the proprietary name is Xarelto®, and the applicant is Janssen Pharmaceuticals, Inc. Micro Labs denies any and all remaining allegations of Paragraph 21.

22. U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders," was duly and legally issued on January 10, 2017.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that the '218 patent bears the title "Prevention and Treatment of Thromboembolic Disorders," and bears an issue date of January 10, 2017. Micro Labs denies any and all remaining allegations of Paragraph 22, including that the '218 patent was duly and legally issued.

23. As set forth in greater detail in the '218 patent, the claims of the '218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, "A method of treating thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke."

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that claim 1 of the '218 patent recites "A method of treating thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke." All other allegations are denied.

24. BIP is the assignee of the '218 patent.

ANSWER: Micro Labs admits that information publicly available in the records of the United States Patent and Trademark Office ("PTO") indicates that Bayer Intellectual Property GmbH is the assignee of the '218 patent. Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 24, and on that basis denies these allegations.

25. Bayer AG is an exclusive licensee under the '218 patent.

ANSWER: Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 25, and on that basis denies these allegations.

26. Janssen is an exclusive sublicensee under the '218 patent.

ANSWER: Micro Labs lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 26, and on that basis denies these allegations.

27. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer may be required, Micro Labs admits that the '218 patent is listed in the electronic version of the "Orange Book" in connection with Xarelto®. Micro Labs denies any and all remaining allegations of Paragraph 27

Infringement by Micro Labs

28. By letter dated March 30, 2017 (the "Micro Labs Notice Letter"), Micro Labs notified BIP and Janssen, among others, that Micro Labs had submitted to the FDA ANDA No. 208334 for Micro Labs' ANDA Products. These products are generic versions of Xarelto®.

ANSWER: Micro Labs admits that by letter dated March 30, 2017 (the "Notice Letter"), Micro Labs notified BIP and Janssen, among others, and that Micro Labs Ltd. submitted ANDA No. 208334 to the FDA for rivaroxaban 10, 15, and 20 mg tablets. Micro Labs denies any and all remaining allegations of Paragraph 28.

29. In the Micro Labs Notice Letter, Micro Labs stated that Micro Labs ANDA Products contain rivaroxaban.

ANSWER: Micro Labs admits that it satisfied all statutory and regulatory requirements for its Notice Letter, including an identification of the active pharmaceutical ingredient in Micro Labs Ltd.'s ANDA Products as rivaroxaban. Micro Labs denies any and all remaining allegations of Paragraph 29.

30. In the Micro Labs Notice Letter, Micro Labs stated that the dosage form of Micro Labs' ANDA Products is tablets. On information and belief, the dosage form of Micro Labs' ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

ANSWER: Micro Labs admits that it satisfied all statutory and regulatory requirements for its Notice Letter, including an identification of the dosage form of Micro Labs Ltd.'s ANDA Products is a tablet. Micro Labs denies any and all remaining allegations of Paragraph 30.

31. On information and belief the proposed labeling form Micro Labs' ANDA Products directs the use of Micro Labs' ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. On information and belief, the proposed labeling for Micro Labs' ANDA Products

further directs the use of Micro Labs' ANDA Products in a manner that satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

ANSWER: Micro Labs admits that Micro Labs Ltd.'s ANDA includes the FDA-required labeling for Micro Lab Ltd.'s proposed ANDA products, and that the labeling speaks for itself. Micro Labs denies any and all remaining allegations of Paragraph 31.

32. In the Notice Letter, Micro Labs did not contest infringement of any claim of the '218 patent.

ANSWER: Denied.

33. On information and belief, the manufacture, use (including in accordance with and as directed by Micro Labs' proposed labeling for Micro Labs' ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products will infringe at least claim 1 of the '218 patent.

ANSWER: Denied.

34. In the Micro Labs Notice Letter, Micro Labs indicated that, in connection with its ANDA No. 208334, Micro Labs had filed Paragraph IV Certifications with respect to the '218 patent.

ANSWER: Micro Labs admits to filing in its ANDA No. 208334 a "Paragraph IV Certification" to the '218 patent. Micro Labs denies any and all remaining allegations of Paragraph 34.

35. The purpose of ANDA No. 208334 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or sale of Micro Labs' ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

ANSWER: Micro Labs admits that Micro Labs Ltd. submitted ANDA No. 208334 to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or sale of Micro Labs' ANDA Products as soon as legally permissible. Micro Labs denies any and all remaining allegations of Paragraph 35.

36. Micro Labs intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately upon approval of ANDA No. 208334, *i.e.,* prior to the expiration of the '218 patent.

ANSWER: Denied.

37. Micro Labs has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Micro Labs has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208334. On information and belief, by such activities, Micro Labs specifically intends to infringe the '218 patent.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits it is aware of the '218 patent. Micro Labs denies any and all remaining allegations of Paragraph 37.

38. On information and belief, Micro Labs plans and intends to, and will, actively induce infringement of the '218 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Denied.

39. On information and belief, Micro Labs knows that Micro Labs' ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Micro Labs' ANDA Products are not suitable for substantial noninfringing use. On information and belief, Micro Labs plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 208334.

ANSWER: Denied.

40. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

ANSWER: Denied.

41. An actual case or controversy exists between Plaintiffs and Micro Labs with respect to infringement of the '218 patent.

ANSWER: Admitted.

42. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Micro Labs Notice Letter.

ANSWER: On information and belief, Micro Labs admits this action was filed before the expiration of forty-five days from the date BIP and Janssen received the Micro Labs Notice Letter, but denies that this action triggers any FDA stay of approval of its ANDA.

CLAIM FOR RELIEF
(Infringement of the '218 Patent)

43. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Micro Labs incorporates its answers to Paragraphs 1-42 as if fully set forth herein.

44. Micro Labs' submission of ANDA No. 208334 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Micro Labs' ANDA Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

45. On information and belief, Micro Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Micro Labs' ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

ANSWER: Denied.

46. Micro Labs intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208334, *i.e.,* prior to the expiration of the '218 patent.

ANSWER: Denied.

47. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

ANSWER: Denied.

48. Unless Micro Labs is enjoined from infringing the '218 patent, actively inducing infringement of the '218 patent, and contributing to the infringement by others of the '218 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Micro Labs denies Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or otherwise with respect to its allegations against Micro Labs.

MICRO LABS SEPARATE DEFENSES

Micro Labs asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Micro Labs does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Micro Labs reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Separate Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST SEPARATE DEFENSE
(INVALIDITY)

The '218 patent and each of its claims are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs Ltd.'s ANDA No. 208334 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '218 patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs Ltd.'s ANDA No. 208334 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '218 patent.

FOURTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

SIXTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

To the extent Plaintiffs' claims are premised on infringement under 35 U.S.C. §§ 271(a)-(c), there is no subject matter jurisdiction over such claims.

SEVENTH SEPARATE DEFENSE
(NO COSTS)

Plaintiffs' claims barred under 35 U.S.C. § 288 from recovering any costs associated with the suit.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Micro Labs reserves the right to plead additional Separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

MICRO LABS LTD., AND MICRO LABS USA, INC.'s COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Micro Labs Ltd. and Micro Labs USA, Inc. (collectively "Micro Labs") by way of their attorneys, hereby state for their Counterclaims against Plaintiffs/Counterclaim-Defendants Bayer Intellectual Property GmbH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs/Counterclaim-Defendants"), the following:

THE PARTIES

1. Micro Labs repeats and incorporates by reference each of the foregoing paragraphs of Micro Labs' Answer and Separate Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent No. 9,539,218 ("the '218 patent")

3. Micro Labs USA, Inc. is a corporation organized and existing under the laws of New Jersey, with a place of business at 104 Carnegie Center, Suite 216, Princeton, New Jersey 08540.

4. Micro Labs Ltd. is a corporation organized and existing under the laws of India, with a place of business at 27 Race Course Road, Bangalore 561 001, India.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

6. Upon information and belief, Plaintiff/Counterclaim-Defendant Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany, and also at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

7. Upon information and belief Plaintiff/Counterclaim-Defendant Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

JURISDICTION

8. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Micro Labs on one hand and each one of the Plaintiffs/Counterclaim-Defendants on the other hand arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

11. This Court has personal jurisdiction over each of the Plaintiffs/Counterclaim-Defendants based, *inter alia,* on the filing of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

12. Venue is proper in this judicial district, under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), in which the Plaintiffs/Counterclaim-Defendants' complaint against Micro Labs is currently pending.

BACKGROUND

13. Upon information and belief, on or about January 10, 2017, the United States Patent and Trademark Office ("PTO") issued the '218 patent.

14. Upon information and belief, Plaintiff/Counterclaim-Defendant Bayer Intellectual Property GmbH is the owner of the '218 patent, Plaintiff/Counterclaim-Defendant Bayer Pharma AG is an exclusive licensee of the '218 patent with respect to rivaroxaban tablets in the United States, and Plaintiff/Counterclaim-Defendant Janssen Pharmaceuticals, Inc. is an exclusive sublicensee of the '218 patent with respect to rivaroxaban tablets in the United States.

15. Plaintiff/Counterclaim-Defendant Janssen Pharmaceuticals, Inc. purports to be the holder of New Drug Application ("NDA") No. 022406 for rivaroxaban tablets, which are marketed in the United States with the trade name Xarelto® and are indicated for treatment of pulmonary embolism (PE), treatment of deep vein thrombosis (DVT), reduction in the risk of recurrence of DVT and PE, prophylaxis of DVT, and reducing the risk of stroke and systemic embolism; and reduction in the risk of recurrence of DVT and PE.

16. On or about July 1, 2011, the U.S. Food and Drug Administration ("FDA") approved NDA No. 022406 for rivaroxaban 10 mg tablets.

17. On or about November 4, 2011, the FDA approved NDA No. 022406 for rivaroxaban 15 mg and 20 mg tablets.

18. Plaintiffs/Counterclaim-Defendants purport and claim to have the right to enforce the '218 patent, and have listed the '218 patent in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") for Xarelto®, and continue to maintain such listing.

19. By listing the '218 patent in the Orange Book, Plaintiffs/Counterclaim-Defendants maintain that an infringement suit could be reasonably asserted against any sponsor of an Abbreviated New Drug Application ("ANDA"), including Micro Labs Ltd., that attempts to seek approval for, and market, a generic version of Xarelto® before the expiration of the '218 and patent.

20. Micro Labs Ltd. has filed an ANDA No. 208334 with the FDA seeking approval for rivaroxaban 10 mg, 15 mg, and 20 mg tablets (the "Micro Labs Ltd.'s ANDA Products"), identifying NDA 022406 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("Micro Labs Ltd.'s ANDA").

21. Because Micro Labs Ltd.'s ANDA seeks FDA approval to market the Micro Labs Ltd.'s ANDA Products before the expiration of the '218 patent listed in the Orange Book, Micro Labs Ltd.'s ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the '218 patent. Each of the Plaintiffs/Counterclaim-Defendants received notification from Micro Labs by letter dated March 30, 2017 ("Micro Labs' Notice Letter") regarding the Paragraph IV Certification in ANDA No. 208334 to the '218 patent, which such notification including Micro Labs' detailed factual and legal bases as to why the commercial manufacture, use, and sale of the Micro Labs Ltd.'s ANDA Products do not infringe the '218 patent because that patent is invalid.

22. Plaintiffs/Counterclaim-Defendants sued Micro Labs in this District for alleged infringement of the '218 patent, which Micro Labs denies.

COUNT I

Declaratory Judgment of Invalidity of the '218 Patent

23. Micro Labs realleges and incorporates by reference the allegations of Paragraphs 1-22 of its counter claims as though fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between Micro Labs and Plaintiffs/Counterclaim-Defendants regarding, *inter alia,* the invalidity of the '218 patent.

25. The claims of the '218 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

26. The claims of the '218 patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '218 patent was disclosed expressly in one or more references and products, which were publicly available before the earliest possible priority date of the '218 patent, including, but not limited to, those references and products disclosed in Micro Labs' Notice Letter, and a person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '218 patent, and would have had a reasonable expectation of success in doing so. Such references and products include but are not limited to: (a) Straub et al., "Substituted Oxazolidinones and Their [Use] in the Field of Blood Coagulation," U.S. Patent Publication No. 2003/0153610, published August 14, 2003; (b) Kubitza et al., "Multiple Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY

59-7939 an Oral, Direct Factor Xa Inhibitor in Healthy Male Subjects," Blood 102: 811a; (c) Kubitza et al., (Abstract#3010, "Single Dose Escalation Study Investigating the Pharmacodynamics, Safety, and Pharmacokinetics of BAY 59-7939 an Oral, Direct Factor Xa Inhibitor in Healthy Male Subjects," Blood, 102: 813a; (d) Kubitza et al., (Abstract PO081, "Single dose escalation study of BAY 59-7939 - an oral, direct factor Xa inhibitor - in healthy male subjects," Pathophysiol Haemost Thromb, 33, suppl2; (e) Aulton, M.E. Pharmaceutics: The Science of Dosage Form Design, Second Edition; (f) Wilkinson, G.R., "Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination," In Goodman and Gilman's the Pharmacological Basis of Therapeutics, McGraw-Hill Professional; 10 Edition (2001), pp. 3-29; (g) Fareed, J., et al. "Pharmacodynamic and Pharmacokinetic Properties of Enoxaparin" Clinical Pharmacokinetics, (2003), 42, pp. 1043-1057; and (h) Leadley, R. J. Jr., et al. "Coagulation Factor Xa Inhibition: Biological Background and Rationale" Current Topics in Medicinal Chemistry (2001), 1, pp. 151-159.

27. There is no objective evidence of non-obviousness of the claims of the '218 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '218 patent.

28. Micro Labs is entitled to a judicial declaration that the claims of the '218 patent are invalid.

COUNT II

Declaratory Judgment of Non-Infringement of the '218 Patent

29. Micro Labs realleges and incorporates by reference the allegations of Paragraphs 1-28 of its counter claims as though fully set forth herein.

30. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual,

substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Micro Labs and Plaintiffs/Counterclaim-Defendants concerning the infringement of the '218 patent

31. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs Ltd.'s ANDA Products described in its ANDA No. 208334 have not infringed, do not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any claim of the '218 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '218 patent that cover rivaroxaban tablets are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation,* 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

32. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs Ltd.'s ANDA Products described in ANDA No. 208334 have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any claim of the '218 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Micro Labs respectfully prays for judgment in their favor and against Plaintiffs/Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the rivaroxaban 10 mg, 15 mg, and 20 mg tablets described in Micro Labs Ltd.'s ANDA 208334

have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '218 patent either literally or under the doctrine of equivalents;

B. Declaring that the claims of the '218 patent are invalid;

C. Ordering that Plaintiffs'/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Micro Labs;

D. Granting Micro Labs judgment in favor of Micro Labs' Counterclaims;

E. Declaring this case exceptional and awarding Micro Labs its reasonable attorneys' fees and costs under 35 U.S.C. § 285;

F. Ordering that Plaintiffs/Counterclaim-Defendants, and their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with them, be preliminarily and permanently enjoined from using the '218 patent to block, hamper, hinder or obstruct FDA approval of Micro Labs Ltd.'s ANDA No. 208334; and

G. Awarding such other and further relief as the Court may deem just and proper.

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